K060636

Bard Urological Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

APR 19 2006

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	C. R. Bard, Inc.
Address:	Bard Urological Division 13183 Harland Dr. Covington, GA 30014
Contact Person:	Julie J. Bassett
Contact Person's Telephone Number:	678-342-4921
Contact Person's Fax:	770-788-5517
Date of Preparation:	March 9, 2006

B. DEVICE NAME:

Trade Name(s):	Palladium-103 Seed Implant Kits
Common/Usual Name:	Brachytherapy seed implants
Classification Names:	90KXK – Source, Brachytherapy, Radionuclide 21 CFR 892.5730

C. PREDICATE DEVICE NAME:

Trade Name(s): TheraSeed® Palladium-103 Implants and BrachySource® Brachytherapy Seed Implants

D. DEVICE DESCRIPTION:

The Pd-103 Seed Implant Kits will be offered using TheraSeed® Palladium-103 Implants, which are produced and marketed commercially by Theragenics, Inc. under the 510(k) K010283. There is no change to the seeds produced by Theragenics and marketed under the name TheraSeed® Palladium-103 devices. These seeds will be packaged in various sterile and non-sterile configurations. These configurations are the same as the predicate described in K043246.

The principles of operation and fundamental scientific technology have not changed. Reference K043246 and K010283 for a detailed description.

TheraSeed® is a registered trademark of Theragenics Corporation®.

E. INTENDED USE:

TheraSeed® Palladium-103 Implants are indicated for tumors with any of the following characteristics:

- Localized,
- Unresectable,
- Low to moderate radiosensitivity.

The tumors may be of the following types:

- Superficial;
- Intrathoracic;
- Intra-abdominal;
- Lung, pancreas, prostate, head and neck;
- Residual following external beam or excision of primary tumor;
- Recurrent.

The intended use has not changed from Theragenics 510(k), K010283.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject device, Palladium-103 Implant Kits, has the same intended use, design and fundamental scientific technology as the predicate devices.

G. PERFORMANCE DATA SUMMARY:

The appropriate testing for the the Palladium-103 Seed Implant Kits was conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

Ms. Julie J. Bassett, RAC
Regulatory Affairs Specialist
C.R. Bard, Inc.
Bard Urological Division
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K060636
Trade/Device Name: Palladium-103 Seed Implant Kits
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXK
Dated: March 9, 2006
Received: March 10, 2006

Dear Ms. Bassett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K060638

Device Name: Palladium-103 Seed Implant Kits

Indications for Use:

TheraSeed® Palladium-103 Implants are indicated for tumors with any of the following characteristics:

- Localized,
- Unresectable,
- Low to moderate radiosensitivity.

The tumors may be of the following types:

- Superficial;
- Intrathoracic;
- Intra-abdominal;
- Lung, pancreas, prostate, head and neck;
- Residual following external beam or excision of primary tumor;
- Recurrent.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060638

(Recommended Format 11/13/2003)

TheraSeed® is a registered trademark of Theragenics Corporation®.